O3

Improve Product Quality

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
O3 (Activity 1)	Improve the quality of medical devices	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a question on a Customer Satisfaction Survey
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will b mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the question, "Do you think that use of the QSIT will result in an improvement of the quality of medical devices produced by the medical device industry? Yes [ ] No [ ] Please explain. " Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses affirm that use of the QSIT would result in an improvement of the quality o medical devices produced by the medical device industry.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct but subjective measurement of the impact of QSIT on the outside "world".	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows firms (stakeholders) to express their views concerning the effect of QSIT on the improvement of product quality.	

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[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
O3	Improve the quality of medical devices.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	Industry responses to a question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses affirm that the use of the QSIT would result in an improvement of the quality of medical devices produced by the medical device industry.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the question: "Do you think that use of the QSIT will result in an improvement of the quality of medical devices produced by the medical device industry? Yes [ ] No [ ] Please explain." A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 12 (63%) No 6 (32%) Other 1 (5%) *(A specific yes or no answer was not provided.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

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Item # O3 (Activity 1)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Do you think that use of the QSIT will result in an improvement of the quality of medical devices produced by the medical device industry? Yes [ ] No [ ] Please explain.

TABULATION of RESPONSES

Form	Yes	No	Other	Comment
1	X			Design Controls and effective corrective and preventive action have made a significant improvement in our facility.
2	X			Constantly improving Quality Systems yield improved products.
3	X			The areas currently targeted provide a very good look at what drives and controls quality of manufacture and service.
4	X			For the same reason as question #5 above. *(Note – The response to #5 was, "It will strengthen the similarity with ISO 9001/EN 46001 requirements because of the four key elements addressed by QSIT".)*
5		X		I still feel some companies may not follow/or care to follow the guidelines as close and adequately as needed.
6	X			Because of the design focus it should help. The greatest manufacturing in the world can" make up for faulty designs.
7		X		See answer on question #6. *(Note – The response to #6 was, "I believe the industry is focused on the Quality Systems Regulation. If I answer yes it would imply we currently do not".)* I think questions ^ & 7 are leading and not valuable as part of the QSIT approach overall.
8	X			Our quality's improvement was partly helped by QSIT.
9			No response	Do not feel qualified to give an opinion.
10	X			Focus on the Quality System subsystems and improvement in those should lead to improved quality, much more reliably than the 'bottom up' approach to correcting defects.
11	X			It specifically forces firms to define and document specific aspects of product develop. & process controls.
12	X			More efficient and directed audits should result in corrected deficiencies at audited sites resulting in improved systems and products.
13	X			As long as good systems are in place.
14		X		Don't believe it will have an impact. Companies either have a quality process, or they don't.
15		X		I know in my firm – our product is already high quality.
16	X			I do not think the QSIT will directly effect the quality of products. The approach to harmonization, however, will allow for consistency between inspectors.
17		X		Companies strive to produce the highest quality products and to meet the regulatory requirements regardless of the method used to audit them.
18		X		I don't believe that the inspection technique will have any affect on the quality of medical devices, but rather the improvement of the quality of medical devices will come from manufacturers implementing ISO 9001 and the quality system regulation.
19	X			I think this approach is a good thorough review of the quality systems. If industry is in compliance with the Quality system regulation it should ensure high quality medical devices. It is also my understanding that this method should decrease inspection time giving inspectors the opportunity to inspect more Device Firms. Timely inspection of all medical manufacturers will help ensure industry compliance and subsequently high quality devices.
TOTAL	12	6	1	